MAY - 2 2001 K011088

510(k) Summary
Special 510(k): Device Modification
SIII Alarm Amplifier *(per 21 CFR 807.92)*

1. SPONSOR/APPLICANT

Stöckert Instrumente GmbH
Lindberghstrasse 25
D80939 Munich
Germany

Contact: Helmut Höfl, Director, Quality Assurance and Regulatory Affairs
Telephone: 011 49 89 323 010
Facsimile: 011 49 89 323 4238

2. DEVICE NAME

Proprietary Name:	SIII Alarm Amplifier
Common/Usual Name:	Amplifier
Classification Names:	Unclassified, Cardiopulmonary bypass heart-lung machine console accessory

3. PREDICATE DEVICE

Stöckert S3 Console (K950990)

4. INTENDED USE

The Stöckert SIII Alarm Amplifier is an optional accessory to the S3 Cardiopulmonary Bypass System Console that, when used in conjunction with other S3 Perfusion System modules, allows the user to augment the audible System alarms (pumps, control accessories, monitoring accessories, etc.) during cardiopulmonary bypass procedures.

5. DEVICE DESCRIPTION

The Stöckert SIII Alarm Amplifier is an accessory module that can be inserted into any free slot in the S3 Console E/P Pack. The user activates the module by pressing the ON button on the module. Activation of the module opens the menu "Alarm Amplifier" on the Central Display Module (CDM). The alert tone volume is adjusted by turning the CDM control knob to the desired value (0 to 5). In an alarm condition, the SIII Alarm Amplifier generates a tone that is synchronized with that of the originating module (pump, control accessory, monitoring accessory, etc.). No hardware or software modifications are required to integrate the SIII Alarm Amplifier into the existing S3 System.

6. BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Stöckert SIII Alarm Amplifier is a new accessory to the S3 Console. The addition of this optional accessory does not change the intended use and technological characteristics (design and operation) of the S3 Console. The addition of the SIII Alarm Amplifier has been validated according to Stöckert Instrumente Design Control procedures, in compliance with FDA Quality Systems Regulations. Testing demonstrates that the SIII Alarm Amplifier performs as intended and the S3 System is not adversely affected. Stöckert Instrumente GmbH, therefore, believes that the S3 Console with SIII Alarm Amplifier is substantially equivalent to the original S3 Console, any differences are minor, and no new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Stockert Instrumente GmbH
c/o Ms. Rosina Robinson
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K011088
Trade Name: Stöckert SIII Alarm Amplifier
Regulatory Class: II (Two)
Product Code: DTQ
Dated: April 9, 2001
Received: April 10, 2001

Dear Ms. Robinson:

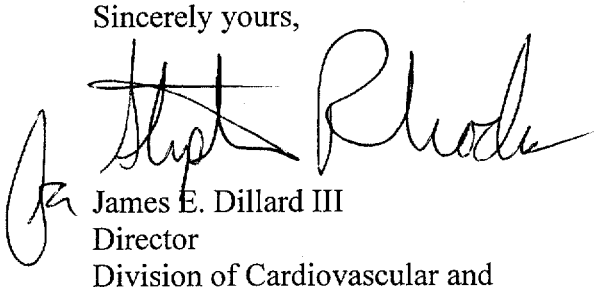
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K011088

Device Name: Stöckert SIII Alarm Amplifier

Indications For Use:

The Stöckert SIII Alarm Amplifier is an optional accessory to the S3 Cardiopulmonary Bypass System Console that, when used in conjunction with other S3 System modules, allows the user to augment the audible System alarms (pumps, control accessories, monitoring accessories, etc.) during cardiopulmonary bypass procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011088

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)